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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/879,217

06/13/2001

Kathleen Danenberg

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6207

23838

7590

02/16/2005

KENYON & KENYON

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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 02/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/879,217	Applicant(s) DANENBERG, KATHLEEN	
	Examiner Jeffrey Fredman	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on December 29, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-14, 16, 23-25 and 27-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-14, 16, 23-25 and 27-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 29, 2004 has been entered.

Status

2. The examiner, in a conversation with Applicants attorney, discussed the filing of a terminal disclaimer. Applicant's attorney indicated that a terminal disclaimer would be filed. Unfortunately, the examiner is under time constraints to act on the case.

Therefore, due to the short time frame, if Applicant has filed a terminal disclaimer, it has not yet been scanned, the fee has not yet been charged, so this action will be mailed. If the terminal disclaimer was filed, it will be treated as responsive to this action without any further action by Applicant, and a Notice of Allowability will be mailed out responsive to entry of the terminal disclaimer.

3. Claims 12-14, 16, 23-25, 27-34 are pending.

Claims 12-14, 16, 23-25, 27-34 are rejected.

Any rejection which is not reiterated in this action is hereby withdrawn as no longer applicable.

Double Patenting

4. Claims 12-14, 16, 23-25 and 27-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6,10,11,17,20,22,27-29,31-35 and 37 of copending Application No. 09/842,111 in view of Gonzalez et al (U.S. Patent 6,015,673).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to determining the effectiveness and safety of a 5-fluorouracil based chemotherapeutic regimen by analyzing the mRNA expression of the DPD gene using the same primer sets. These claims differ only in the step of determining the 5-fluorouracil based regimen based upon the DPD mRNA concentration.

Gonzalez teaches a method for determining the level of DPD gene expression in a tissue to determine the safety of a 5-fluorouracil based chemotherapeutic regimen comprising the steps: (see column 14, lines 41-51, also see column 27, lines 14-27, here the tissue is cultured fibroblasts derived from skin biopsies),

- (a) obtaining a sample from a patient (column 14, lines 41-52)
- (b) isolating mRNA from the sample (column 14, lines 52-67),
- (c) amplifying the mRNA with primers which are substantially identical to SEQ ID NO: 1 and 2 (see column 55, SEQ ID NO: 5)

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to apply the DPD analysis method of copending Application 09/842,111 to determining the safety of 5-fluorouracil based

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chemotherapeutic regimens since Gonzalez states "The method and compositions are useful for identifying persons who are at risk of a toxic reaction to the commonly employed cancer chemotherapy agent 5-fluorouracil (see column 1, lines 8-10)". It is noted that these claims were not subject to restriction from one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim Rejections - 35 USC § 103

6. The rejection of claims under 35 U.S.C. 103(a) is withdrawn in view of the declaration and unexpected results therein, as commensurate in scope with the claims which require the specific methods and SEQ ID Nos.

Response to Declaration

7. The Declaration under 37 CFR 1.132 filed December 29, 2004 is sufficient to overcome the rejection of the claims based upon 35 U.S.C. 103 since the evidence presented, particularly the data on page 4, provides direct evidence of an unexpected

result using the primers of the claimed invention. This evidence rebuts the prima facie case of obviousness as a secondary consideration and renders the claims novel and unobvious over the prior art (though the double patenting rejection remains).

Response to Arguments

8. Applicant's arguments with respect to the claims, filed December 29, 2004, indicate that Applicant will file a terminal disclaimer if 09/842,111 is issued. Since that application was allowed, the terminal disclaimer is necessary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey Fredman

JEFFREY FREDMAN
PRIMARY EXAMINER